

### REMARKS

In the instant Action, claims 3-12 and 14 are listed as pending.

• Response to nonstatutory obviousness-type double patenting rejection

Claims 3-12 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent No. 7,268,213. Without addressing the substantive merits, *vel non*, of this rejection, but solely in order to place the instant application in a condition for allowance, Applicant has canceled claims 3-10.

Having canceled claims 3-10, Applicant traverses this rejection with respect to claims 11 and 12. All of the compounds of claim 11, as currently amended, are outside the scope of claim 1 of U.S. Patent No. 7,268,213. Specifically, all of the compounds of Claim 11 have position 38 substitutions – *i.e.*, Scr<sup>38</sup>, Asn<sup>38</sup>, Gaba<sup>38</sup>, His<sup>38</sup>, D-His<sup>38</sup>, β-Ala<sup>38</sup>, Gly<sup>38</sup> – that are not disclosed or suggested by claim 1 of U.S. Patent No. 7,268,213. In fact, Applicant has deleted the following two compounds from claim 11, as indicated hereinabove, in order to remove all possible overlap with claim 1 of U.S. Patent No. 7,268,213:

(Aib<sup>8,35,37</sup>, Arg<sup>26,34</sup>, Phe<sup>31</sup>, Ava<sup>38</sup>)hGLP-1(7-38) NH<sub>2</sub>; (SEQ ID NO:17)

(Aib<sup>8,35,37</sup>, Arg<sup>26,34</sup>, Ava<sup>38</sup>)hGLP-1(7-38) NH<sub>2</sub>; (SEQ ID NO:18).

Applicant further submits a declaration from Dr. Jundong Zhang under 37 C.F.R. §1.132 to introduce experimental data showing the surprisingly long half-lives of the compounds of claim 11, as currently amended. As noted in the instant Application, at page 2:

GLP-1 is, however, metabolically unstable, having a plasma half-life ( $t_{1/2}$ ) of only 1-2 min *in vivo*. Exogenously administered GLP-1 is also rapidly degraded (Deacon, C.F., et al., Diabetes 44:1126-1131, 1995). This metabolic instability limits the therapeutic potential of native GLP-1. Hence, there is a need for GLP-1 analogues that are more active and/or are more metabolically stable than native GLP-1.

When the surprisingly long half-lives of the compounds of claim 11, as currently amended, are considered together with the previously submitted declaration of Dr. John

E. Taylor (*See* Applicant's reply to the non-final Office Action previously submitted on November 20, 2009), which introduced experimental data showing the GLP-1 receptor binding activity of the compounds of claim 11, as currently amended, it is evident that the compounds of claim 11, as currently amended, provide a novel and non-obvious solution to the technical problem which Applicant set out to achieve in the instant Application.

With respect to claim 12, in view of the fact that claim 12 is currently amended to depend on claim 11, which claim is also currently amended to be directed solely to those compounds that are outside the scope of claim 1 of U.S. Patent No. 7,268,213, and whose inventiveness is further supported by surprisingly long half-lives, it is respectfully submitted that claim 12, as amended, is non-obvious over claim 1 of U.S. Patent No. 7,268,213.

- Response to rejection under 35 U.S.C. §112

Claim 14 is rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Without addressing the substantive merits, *vel non*, of this rejection, but solely in order to place the instant application in a condition for allowance, Applicant has canceled claim 14.

Applicant respectfully requests that the rejections set forth in the instant Action be reconsidered and withdrawn and that this application be passed to issue. Prompt and favorable action is earnestly solicited.

Respectfully submitted,

Date: November 1, 2010

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